DOWNEY·SMITH·FIER
STATE & LOCAL TAX

November 12, 2014

Susanne Buehler
Chief, Tax Policy Division
Sales and Use Tax Department
State Board of Equalization
450 M. Street
Sacramento, CA 94279-0092

Re: Clarification regarding final BTC Comments - Proposed Regulation 1591, *Medicines and Medical Devices: DSF's Proposed Changes do not create any revenue impact*

We have received the final Issue Paper and Revenue Estimates for Regulation 1591 to be discussed at the up-coming Business Taxes Committee meeting on November 19, 2014. We are planning to attend the meeting; however, we want to bring to your attention an error in the final materials that present a Revenue Estimate for Alternative 2 that is not accurate and should not be applicable to our proposed language.

As background, DSF participated in the Interested Party process to assist Staff to address the issues and clarifications requested by the Board following its decision in our appeals case involving Breast Tissue Markers ("BTMs"). During this process, we are not attempted to exempt any specific product nor have we intended to overturn any long-standing position regarding the treatment of any single product. Our objective during this process has been to assist with clarifying the regulatory language, address the uncertainty and confusion experienced during the BTM appeal process and provide a simple bright-line definition.

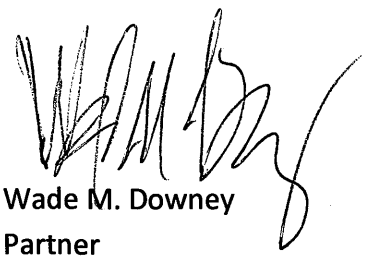
The revenue estimate prepared by staff for Alternative #2 implies that the proposed language prepared by Downey, Smith & Fier intends to alter the taxability of the Port-A-Cath product. All versions of the existing and/or proposed Regulation 1591(c) begin "Except as otherwise provided in subdivision (b)...". The Port-A-Cath product is specifically addressed as a <u>taxable product</u> in Regulation 1591(b) to which DSF proposed no change. Accordingly, the revenue estimate for Alternative #2 that is based on this product being exempted is not accurate; it does not apply to our proposal.

Ms. Susanne Buehler
Proposed Changes to Regulation 1591-Medicines and Medical Devices
Downey, Smith & Fier's - Clarification
November 11, 2014

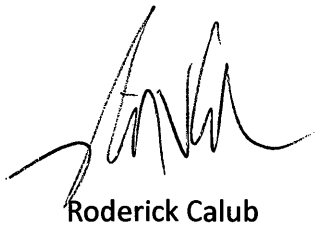
As included in our Exhibit 3 in the BTC materials, the BTM appeal related to the application of 1591(a)(9)(A) involving two elements: 1) the definition of FDA approval; and 2) the scope of subsection (c). Staff did an excellent job addressing the first element, as well as specifically including BTMs in (b). However, Alternative 1 does not address the scope of (c) as it applies to fully implanted products. The added reference to (b) and (c) in (a)(9) does not clearly explain the scope of the exclusions in (c). Our proposed language was viewed as the simplest way to address this second element yet maintain the integrity of the regulation and not expand the definition of medicine (i.e., exclude Port-A-Cath products). Alternative #2 clarifies that (c) does not exclude products that are fully implanted to diagnose, cure, mitigate, treat or prevent disease. This is consistent with the decision involving diagnostic tissue markers as well as how the medical community has treated implanted diagnostic products (as exempt). As such, we would not expect a revenue impact related to Alternative #2.

We look forward to participating in the conclusion of this process. If you have any questions or would like to discuss, please call me at (562) 249-6002.

Sincerely,



Wade M. Downey
Partner
Downey, Smith & Fier



Roderick Calub
Healthcare, Senior Manager
Downey, Smith & Fier

Cc: Michael A. Patno, Program Policy Specialist, BTC